Implementing personalized health care

INITIATIVES IN THE EU, KOREA AND CANADA

On September 25, 2018, the International Conference on Personalized Health Care presented a panel on International Initiatives for Implementation of Personalized Health Care. Speakers from France, the Republic of Korea and Canada described approaches being taken to advance personalized care. Oncology Exchange *presents key points from their talks.*

PRESENTATION SUMMARY: Personalized medicine: A European Union perspective

Jean-Luc Sanne, PhD, Director General, Innovative and Personalized Medicine Unit, Research and Innovation Directorate, European Commission

The European Union (EU) includes 28 countries. Its governing institutions include the European Council, European Parliament, the Council of the EU, and the European Commission. Competences pertaining to personalized healthcare include some that are exclusive to the EU institutions, and others that are shared competences. EU institutions also play support, coordination and supplementation role in areas such as health and education.

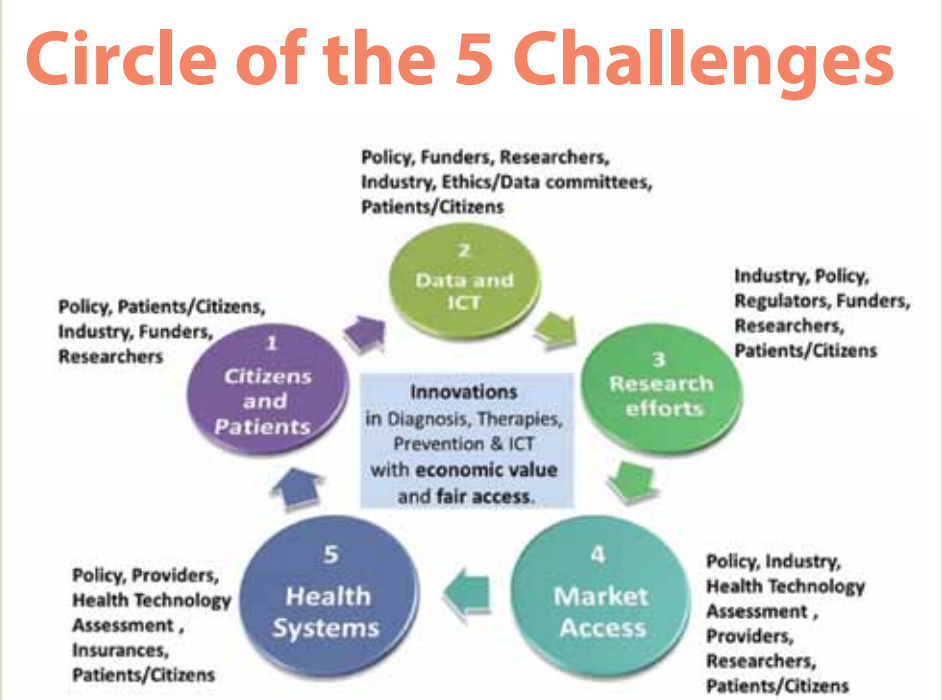
The EU definition of personalized medicine was agreed by the EU Council in 2015. It states:

"Personalized medicine refers to a medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention. Personalized medicine relates to the broader concept of patient-centred care, which takes into account that, in general, healthcare systems need to better respond to patient needs."

EU activities on personalized medicine began with preparatory workshops in 2010. A strategic research and innovation agenda was developed and the International Consortium of Personalised Medicine was launched in 2016. The Consortium brings together more than 30 funding bodies from EU member states and beyond, including Canada, as well as health, science and education ministries and regional authorities. The Consortium 2017–2022 action plan involves supporting the personalized medicine science base through a coordinated approach to research, including research on the benefits of personalised medicine to citizens and healthcare systems. It also strives to pave the way for personalized medicine approaches for citizens. ERA PerMed was created as a consortium of countries and regions and was co-founded by the European Commission to align national research strategies, reinforce the competitiveness of European players and enhance collaboration between EU and non-EU countries. In 2018, funding agencies launched the first call for collaborative innovative research projects in personalized medicine.

The Consortium Action Plan calls for research and support activities to address the 5 following challenges:

FIGURE 1. Challenges identified at the EU 2016 Personalized Medicine Conference.



ICT: information and communication technologies.
Source: PerMed (2016) Shaping Europe's Vision for Personalised Medicine. Available at: https://www.permed2020.eu/_media/PerMed_SRIA.pdf.

1. Patient awareness and empowerment: This challenge involves bringing about a cultural change by emphasizing health literacy and educating healthcare providers to better involve patients in medical research. "We should not think of (engaging) patients as an alibi to get their data," stressed Dr. Sanne. Patient education in the process of medicine development is being addressed in a project called the European Patients' Academy, supported by industry and the EU (see https://www.eupati.eu). EUPATI has created patient training courses, issued guidance on patient involvement in R&D and launched an online educational toolbox.

Another component of this challenge is being addressed through the European Reference Networks, which seeks to facilitate the exchange of clinical data on patient cases throughout EU networks to increase access to expertise. National healthcare providers are able to seek advice from a specific European reference network to guide their diagnosis and care plan. At present, 370 hospitals and over 900 expert units in 26 countries are involved.

2. Integration of information and communication technology and big data in health research and healthcare: This challenge includes building infrastructure for life sciences information, and enabling data sharing and reuse according to FAIR (findable, accessible, interoperable and reusable) data principles. The goal is to enable the digital transformation of health and care, and provide e-health digital services. The Digital Single Market communication in April 2018 addresses secure citizen access to their health data, including across borders, and citizen empowerment through use of digital tools for feedback and person-centred care. Technical specifications need to be developed for secure access and cross-border exchange of health data. Among researchers, the European Open Science Cloud aims to bring together current and future data infrastructures to facilitate collaborative research, including across disciplines. In April 2018, 13 European countries signed a declaration for delivering cross-border access to their genomic information, and aim to provide access to at least 1 million sequenced genomes in the EU by 2022.

3. Translation of research into clinical and health applications: The challenge here is to better integrate and evaluate omics information into clinical research, better understand disease mechanisms, and identify and validate biomarkers. Data management and IT solutions, and support of policies and healthcare systems, assumed a greater part of these efforts after 2015. A number of resources, such as biobanks and translational medicine infrastructures, are developing to support this work.

4. Bringing innovation to the market and to patients: An appropriate regulatory framework and support and incentives from regulatory agencies are a primary aspect of this challenge. The EU regulatory framework includes legislation and regulations governing pharmaceutical marketing authorization, data protection, medical devices and clinical trials. The European Medicines Agency launched the PRIME (PRIority MEdicines) scheme to enhance support for the development of medicines that target an unmet need, through early dialogue between regulators and developers, to optimize development plans and speed evaluation so medicines can reach patients earlier. Other measures have been taken to strengthen Europe's healthcare industry through public-private partnerships, support for small and medium-sized enterprises, better access to loans, and a pilot initiative to bring together scientists and entrepreneurs.

5. Potential impact of personalized medicine on the sustainability of healthcare systems: The EU recognizes the need for health technology assessment to keep up with advances and support the adoption of new technologies that improve population health and, by extension, the sustainability of health systems.

In conclusion, Dr. Sanne stressed that a new paradigm is being driven by science and technology and will require that healthcare adapt to a patient-centred approach. Disruptive technologies, generation and use of large amounts of genomic, biologic and other types of data, and progress in the understanding of health and disease have enabled rapid development of personalized medicine. However, the adaptation of health systems and methodologies to understand better the value of this new approach are needed. Education and training are needed, and challenges related to data quality, accessibility and compatibility must be addressed. The compatibility of personalized medicine approaches and system sustainability needs to be assessed in an ongoing manner. Dr. Sanne calls for socioeconomic studies and pilot implementation projects to provide evidence.

PRESENTATION SUMMARY: Personalized medicine and the reform of universal health coverage: lessons from the Republic of Korea

Myongsei Sohn, PhD, Professor at Yonsei University College of Medicine, Seoul, Republic of Korea

Dr. Myongsei Sohn, who is Former President of the Health Insurance Review and Assessment Service, discussed the challenges personalized medicine presents in a context of universal coverage. Social investment in national health insurance, coupled with the efficient utilization of finances, are major mechanisms for adopting new health technologies that aim to benefit patients, improve social welfare and promote health industries.

In Korea, National Health Insurance (NHI) is on a single purchaser/payer model. Five percent of healthcare providers are public and 95% are private, signing mandatory contracts with the NHI and undergoing mandatory performance assessments. The country faces familiar challenges of increasing life expectancy, low birth rates, rising individual purchasing power, and an increasing burden of disease. While wanting to provide the benefits available from personalized medicine, there are ethical concerns that it not

affect access or increase social disparities.

A key challenge in reforming the national health insurance system to adopt personalized medicine lies in accumulating evidence during the "transition" period when high uncertainty around benefit exists. To address this challenge, Korea has adopted a selective benefit coverage system that provides for high copayments when the cost-effectiveness of a drug or technology is not yet established. Before adopting novel personalized healthcare services into the public payment system, those services are incorporated in the design of the insurance regime in various ways. Considerations at the initial stage include the selection of services for temporary demonstrative coverage, the purchasing rate, payment system and target population, as well as designation of competent hospitals and service providers. Healthcare services are monitored, and operating results of the new services are reviewed and assessed for efficacy, cost-effectiveness and safety.

In order to assure efficient use of health financing for personalized healthcare services, each initial purchasing model is revised through the planned feedback system. Every 5 years or more, at the discretion of the Minister, the drug or technology is reassessed and copayments are reduced in line with evidence of benefit. The Health Insurance Review and Assessment (HIRA) Service recently established a demonstrative payment system for anticancer drugs and gene-panel testing using planned systematic feedback. For example, glutamic-pyruvic transaminase (GPT) testing was introduced with 50% copayment in 2017; the level of copayment stands to change as evidence of benefit accumulates.

For precise analysis, big data obtained through a network of hospitals and housed in the HIRA archive may be used.

The system permits the accumulation of data on use, as providers submit data needed to assess selective benefit coverage over time; the incentive for physician participation is clear, said Dr. Sohn: "If physicians don't provide data, they may be blocked from using therapies with their patients."

The NHI functions as a major social investment: expanding coverage while reducing patient copayments for care with proven efficacy; consolidating bargaining power in a single purchaser; and building a system to reflect the analysis of big data. "Korea has 50 years of health data and insurance claims data," stated Dr. Sohn. He sees future challenges in distinguishing essential and nonesssential health services. He also considers a possible evolution to medical "prosumer" patients, who allow government to use data in exchange for receiving benefits.

PRESENTATION SUMMARY: Toward regulating advanced technology health products in Canada

David K. Lee, PhD, Chief Regulatory Officer, Health Products and Food Branch, Health Canada

Global advancements in science and technology have stimulated the development of a wide variety of innovations that are challenging current regulatory frameworks for health products in Canada and around the world. Health Canada is pursuing efforts to modernize the regulatory frameworks designed to assure Canadians of the safety, efficacy and quality of health products. Regulatory modernization efforts are geared toward identifying barriers and challenges innovators face with the current system and developing new approaches to regulate advanced technology health products.

To support these regulatory modernization efforts, Health Canada has taken an in-depth look at drivers and trends that are shaping the future health landscape. Using a variety of methods (literature search, interviews, consultations, etc), Health Canada's Health Products and Food Branch staff have undertaken extensive work to understand this future health landscape. Insights from this exercise are being used to inform policy directions and decisions.

At ICPHC, Dr. Lee described these horizon-scanning activities, discussed findings related to increasing the precision and personalization of health systems and care, and provided information about future engagement opportunities.

The purpose of horizon scanning, defined by Policy Horizons Canada, is to identify "drivers and changes in the domestic and international environments that could affect government policy and programs. It is not trying to predict the future, but rather explores drivers and the range of plausible futures that may emerge." Health Canada's guiding principles in horizon scanning are to consider a wide range of drivers and sources, discuss internally and externally and scan regularly, focus on the potential for disruption, and consider the needs of end users. Horizon scanning enables the prioritization of high impact advances, which informs strategic and operational activities.

The main drivers of change include environmental pressures, social and population-based drivers, advances in science and technology, the evolution of regulatory science, and political, international and economic factors. The insights that have been developed reflect a future healthcare landscape where:

- There will be data-generating and data-reliant systems for all aspects of health.
- Citizens will be empowered with the information and resources to manage individual care.
- Systems and services will be individualized.
- Products will be increasingly complex, and innovations will blur product lines and defy standard classification.
- Manufacturing and supply chains will be local, connected and accountable.
- New technologies, R&D practices and trial designs will challenge existing review processes.

Key drivers of this future landscape include genetic testing, omics and advanced cellular technologies, and also technologies like bioprinting, sensors and implants. A democratization or decentralization of care, and increasing connectivity, will also drive change, notably creating possibilities for the collection of real-world evidence, peer-to-peer platforms and direct-to-consumer testing.

The horizon-scanning exercise identified challenges and opportunities arising from this landscape. New technologies may blur the lines between the practice of medicine, health systems and regulatory authorities, and bring changes to the regulator's role in safeguarding citizens and ensuring safety and efficacy. They have implications for activities such as market authorization, reporting and surveillance. This means that Health Canada will need to consider how it, as a regulatory authority, will change, and what safeguards and stewardship functions will ensure that health products are safe, effective and of high quality. At the same time, regulations will need to become flexible and open to nonstandard premarket evidence standards and products. As researchers are increasingly collaborating at a global scale, Health Canada scientists will need to contribute to these larger networks, maintain the skills needed to review submitted evidence and develop pathways to accommodate innovative evidence and products.

In its 2017 report, Investing in a Resilient Canadian Economy, the Advisory Council on Economic Growth set out the challenge for regulatory agencies, stating: "Regulation has to be agile and adaptive enough to address the ways that innovative companies will continuously rewrite the rules of competition, ensuring sufficient oversight to protect public interest without posing obstacles to innovation." Dr. Lee suggests that Canada's regulatory systems must, to become more responsive, remove old regulations that are redundant or create unnecessary barriers to innovation, simplify and strengthen oversight and provide flexibility to enable product innovation, and consider current and new approaches to better regulate advanced technologies in health.

Health Canada is proactively seeking to engage with stakeholders involved in the creation, testing, design and deployment of advanced technology health products to help inform and develop the policies that will shape a future regulatory system that is intended to provide Canadians with timely and safe access to innovations that can help improve their health.